K031884

JUN 30 2003

RYAN TELEMEDICINE

510(k) Summary for *netwave* Interferential Stimulator

1. Sponsor

Ryan Telemedicine, LLC
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Costa Mesa, Ca 92627

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Telephone: (800) 495-7926
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Date Prepared: June 12, 2003

2. Device Name

Proprietary Name:	*netwave* Interferential Stimulator
Common/Usual Name:	Electrical Muscle and Nerve Stimulator
Classification Names:	Interferential Current Stimulator, Powered Muscle Stimulator
Classification Panel:	Physical Medicine
Panel/Product Code:	890.5850 / IPF

3. Legally Marketed Device to Which Equivalence is Claimed

Proprietary Name:	RTM 1000 Interferential Stimulator
Common/Usual Name:	Electrical Muscle and Nerve Stimulator
Classification Names:	Interferential Current Stimulator, Powered Muscle Stimulator
Classification Panel:	Physical Medicine
Panel/Product Code:	890.5850 / IPF

4. Intended Use

netwave Interferential Stimulator is a multifunction device intended to be used for muscle and nerve stimulation using either of its two therapy modes, Interferential Current Stimulation or Neuromuscular Electrical Stimulation.

In the Interferential Current Mode, *netwave* is indicated for the following conditions:

- Symptomatic relief of acute pain
- Symptomatic management and relief of chronic pain
- Adjunctive treatment for the management of post traumatic and Post-surgical pain

In the Neuromuscular Stimulation Mode, *netwave* is indicated for the following conditions:

- Relaxation of muscle spasms;
- Prevention or retardation of disuse atrophy;
- Increasing local blood circulation;
- Muscle re-education;
- Immediate post surgical stimulation of calf muscles to prevent venous thrombosis; and
- Maintaining or increasing range of motion.

5. Device Description

The Ryan Telemedicine *netwave* Interferential Stimulator is a battery powered (rechargeable) device intended for clinic, and outpatient use. Prescribed by a physician, *netwave* gives the clinician a variety of electrotherapy modes to treat a range of indications. *netwave* is designed for clinician and patient ease of use and provides safe and effective dispensing of the desired electrotherapy treatment. *netwave* incorporates the following features:

- Two independent stimulation channels, which provide true interferential current and neuromuscular stimulation.
- Continuous or pulsed stimulation. Adjustable sweep and ramp times.
- Adjustable amplitude and frequency
- Four programmable therapy protocols
- Five preset therapy protocols
- Adjustable on and off times
- Pause button to allow temporary cessation of treatment and a resume button to allow the continuance of treatment. When a treatment session is paused, the timer does not countdown. Upon resumption of treatment, the timer resumes its countdown and the amplitude (intensity) is reset to zero.
- Easy to connect, easy to handle, patient lead wire/cable assembly with a "one way" connector and color coded lead wires contribute to improved patient experience and improved therapy outcomes.
- Timed therapy sessions.
- Robust rechargeable Nickel Metal Hydride battery system with rapid recharge (85% recharge in 30 minutes – full charge in 2 hours)
- Charging / communicating cradle which serves as "home base" for *net*wave and provides a simple recharging system for the user/patient. The use of the charging cradle ensures *net*wave is always at peak battery power.
- The communication functions of the cradle allow for the uploading of patient data (compliant with HIPAA regulations) to an Internet data server for use by the patient's authorized caregivers. NO INDIVIDUALLY IDENTIFIABLE PATIENT DATA is transmitted.
- *net*wave user interface incorporates a touch screen Liquid Crystal Display (LCD) as the main device/user interface.

6. Basis for Substantial Equivalence

netwave is substantially equivalent to the legally marketed device and is similar in design, features and function and provides the intended therapy in a safe and effective manner. Both devices offer identical preprogrammed treatment protocols and the clinician or patient can choose one or more of these pre-set options. Furthermore, both allow the clinician to customize a treatment protocol for each individual patient within the parametric ranges and save the treatment into memory.

Bench testing was performed on the marketed device and *netwave* and the therapy output and performance characteristics for both units was identical.

7. Differences Between the Marketed Device and *netwave*

netwave incorporates several improvements over the legally marketed device, including:

- Simplified battery charging system. There is no need to connect a charging cable to the device. The user places the device in the charging cradle to begin the charging process.

- Equal recharge time at a lower charging temperature. The battery charging circuitry has been removed from the device and relocated in the charging cradle.

- Improved safety due to the device software preventing therapy treatment while connected to wall current (recharging). Once the stimulator is removed from the cradle it is no longer connected to wall current.

- Greatly simplified user interface with a minimum number of steps to begin therapy treatment.

- Easy to read interface screens with full descriptions of available options and settings.

- Large "Pause" and "Quit" buttons on the interface ensure quick cessation of treatment.

- The stimulator now incorporates an "Initial Activation Code" to be entered by the user. The code is embedded in the instruction manual in the "Warnings and Precautions" section thereby encouraging the user to read the Indications, Contraindications, Precautions, Warnings and Adverse Effects section of the Instruction Manual.

- The stimulator includes a HIPAA "Patients Rights" acknowledgement process which encourages the education of the patient as to their patient rights.

- Treatment compliance data is recorded in greater detail and is available within 24 hours of the first treatment.

- Bi-directional communication system which enables greater communication between patient, Physician and Clinician and virtually immediate reporting of patient compliance data.

- Communications are fully compliant with HIPAA regulations and are secure using HTTPS (security) protocols.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2003

Ryan Telemedicine
c/o Mr. Donald James Sherratt
Intertek Testing Services
70 Codman Hill Rd
Boxborough, MA 01779

Re: K031884
Trade/Device Name: Interferential Stimulator, Model n*et*wave
Regulation Number: 21 CFR 890.5850
Regulation Names: Powered muscle stimulator
Regulatory Class: Class II
Product Codes: IPF
Dated: June 16, 2003
Received: June 18, 2003

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

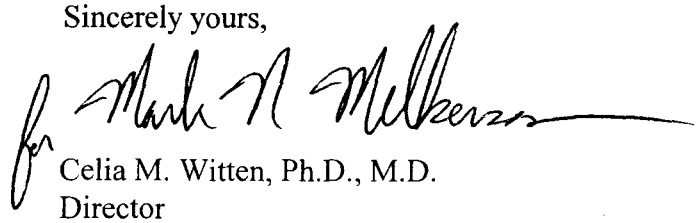
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K031884

Device Name: netwave Interferential Stimulator

Indications For Use:

Interferential Current Mode: Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post surgical and post traumatic pain.

Neuromuscular Stimulator Mode: Relaxation of muscle spasm, increasing local blood circulation, maintaining or increasing range of motion, preventing or retarding disuse atrophy, muscle re-education, and immediate post surgical stimulation of calf muscles to prevent venous thrombosis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031884

(Optional Format 3-10-98)